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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,475	09/10/2003	Lance Schlipalius	M 5767A-NHG/CA	3437

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COGNIS CORPORATION
PATENT DEPARTMENT
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AMBLER, PA 19002

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,475	SCHLIPALIUS ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed April 6, 2005 have been received and entered into the application.

Action Summary

The rejection of claims 1, 3-5, 14 and 15 under 35 U.S.C. 102(e) as being anticipated by Akamatsu et al. (U.S.Patent No. 5,780,056) evidenced by Ogawa et al. (U.S.Patent No. 5,004,756) is maintained for the reasons stated in the previous Office Action and modified version as follow to exclude cancelled claim 2.

The rejection of claims 6-13 and 16 under 35 U.S.C. 103(a) as being unpatentable over Akamatsu et al. (U.S.Patent No. 5,780,056) is maintained for the reasons stated in the previous Office Action and modified version as follow to include the limitation set forth in currently amended claims 1 and 16.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 3-5, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Akamatsu et al. (U.S.Patent No. 5,780,056) evidenced by Ogawa et al. (U.S.Patent No. 5,004,756).

Akamatsu et al. on column 3, lines 5 through 40, teach Applicants' carotenoid composition comprising lycopene suspended in medium chain triglyceride (having 8-12 carbon atoms (such as caprylic acid, capric acid and lauric acid)). Akamatsu et al. teach the antioxidant is blended in an effective amount, typically 0.01 to 15% by weight based on the weight of the microcapsule, which encompasses the amounts set forth in claims 14 and 15. (column 3, lines 57-59).

Applicants' limitation of claim 2 wherein the limitation of making the triglyceride is not given patentable weight as written because the claim is drawn to a composition claim. Further, the limitation is a product by process and since the product as claimed is still the same product as taught by the prior art. Therefore, claim 2 is still anticipated by Akamatsu et al. (column 3, lines 5-40).

Ogawa et al. disclose that triglycerides of medium-chain fatty acid have 8-12 carbon atoms (such as caprylic acid, capric acid and lauric acid), and normally abbreviated as MCT.

Ogawa et al. is brought in as an extrinsic evidence to show that medium-chain fatty acid utilized by Akamatsu et al. are well-known by Ogawa et al. as having 8-12 carbon atoms (such as caprylic acid, capric acid and lauric acid) as claimed by Applicants.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 6-13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akamatsu et al. (U.S.Patent No. 5,780,056).

Akamatsu et al. as applied as above and additional teaching as follows.

Akamatsu et al. on column 3, lines 5 through 40, teach Applicants' carotenoid composition comprising lycopene suspended in medium chain triglyceride. Akamatsu et al. report that lycopene has anti-carcinogenic activity. (column 3, lines 25-32). Akamatsu et al. teach that the antioxidants to be utilized in the composition include tocopherol. (column 3, lines 47-50). Akamatsu et al. also teach on column 2, lines 5-17 that their composition is provide high strength of carotenoids to prevent the carotenoids from being oxidized or deteriorated for a long time and in a stable manner. Akamatsu et al. teach the effective amount of 0.01 to 15% by weight, which encompasses the amounts set forth in claims. Akamatsu et al. teach that the amount of carotenoids and edible oil (medium chain triglyceride) are mixed in a weight ratio between 20/80. (column 3, lines 40-43).

The difference between above reference and Applicants' claimed invention is to administer Akamatsu's composition to the host to provide a bioavailable antioxidant (lycopene) and the amounts of lycopene.

However, the skilled artisan would have been motivated to employ Akamatsu's composition to a host i.e. cancer patients, to benefit its delivery of high strength of lycopene which is not vulnerable to oxidation and deterioration in the treatment of cancer. The amounts of active agents (lycopene) to be used, the pharmaceutical forms, e.g., tablets, etc; mode of administration, flavors, surfactant, types of tocopherol to be selected are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and Akamatsu et al. teach the tocopherol in general therefore it encompasses any one of the tocopherol including alpha, beta and delta.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Response to Arguments

Applicants' arguments filed April 6, 2005 have been fully considered but they are not persuasive. Applicants argue that as amended herein, the Applicants' claimed invention is directed to carotenoids compositions comprising lycopene suspended or dispersed in a medium-chain triglyceride, wherein the medium-chain triglyceride is derived from esterification of a substantially pure medium chain fatty acid and substantially pure glycerol ad the use of medium chain triglycerides derived from the

esterification of substantially pure glycerol and fatty acids, rather than natural source oil extracted with solvents, reduces the presence of impurities that may cause or induce oxidation of the carotenoids. This is not persuasive because Akamatsu teaches the medium chain triglycerides is typical synthetic oil and the medium chain triglycerides does not required to be extracted from natural source. (column 3, lines 37-41). Therefore, Akamatsu's teaching clearly anticipates Applicants' claimed invention since it teaches all the required components (lycopene suspended in an edible oil such as medium-chain triglyceride). Applicants argue that the long term stability of a carotenoids composition containing a medium chain triglyceride prepared by esterifying fractionally distilled fatty acids and highly pure glycerol is far superior to a carotenoids suspended in soya bean oil as can be seen from Example 1, which begins at line 15, page 9 of specification. This is not persuasive because Akamatsu teaches same composition comprising lycopene suspended in an editable oil such as medium-chain triglyceride from a synthetic oil. Moreover, Applicants' data (Example 1) have been carefully reviewed but not persuasive because the data (Example 1) does not show the comparative testing with the closest prior art as cited. Applicants' data (Example 1) does not indicate how the medium chain fatty acid derived from esterification of a substantially pure medium chain fatty acid and substantially pure glycerol differ from the very same component (medium chain fatty acid) utilized by Akamatsu's composition. Accordingly, Akamatsu clearly anticipates the claimed invention since it teaches all required component of the Applicants' invention without side-by-side comparison.

That applicants may have determined a process of obtaining a composition does

not alter the fact that the composition has been previously obtained by the prior art. The ultimate resulting composition is the same. It is well settled in patent law that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. See MPEP § 2123. The court in In re Thorpe held, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

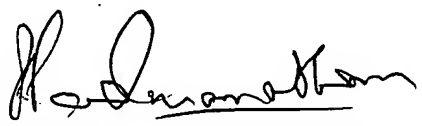
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
June 13, 2005